A QUICK GUIDE TO PATENT LAW AND RECENT DEVELOPMENTS IN THE FIELD

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Executive Summary: The Framers of the U.S. Constitution believed that codifying intellectual property rights at the federal level was important to economic independence, innovation, and domestic growth. Article I, Section 8 declares that Congress has the power "to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." Intellectual property in the United States encompasses four broad categories: patents, trademarks, copyrights, and trade secrets. A patent is a property right granted to an inventor that allows the inventor (or assignee) to exclude others from "making, using, offering for sale, or selling" the invention for a limited time. Patents play an essential role in the economy by creating limited legal monopolies for inventors and developers, which incentivize investment in creativity, innovation, and production. In exchange for these legal monopolies, patent owners disclose their inventions to the public, contributing to continued advancements in science, engineering, medicine, and more. A well-functioning and efficient patent system is critical to invention and innovation.

I. INTRODUCTION

A patent is intended to protect new processes, machines, and/or products as codified in the 1952 Patent Act.[1] A patent is an exclusive right granted by the federal government that allows a person to prevent others "from making, using, offering for sale, or selling" an invention in the United States or importing it into the country.[2] To obtain a patent, the inventor must disclose technical information about the invention in the form of a patent application. As a reward for disclosure, patent owners obtain exclusive rights to their inventions. There are two key limitations on this monopoly. First, a patent does not give the inventor an *affirmative* right to make, use, or sell the invention.[3] Second, a patent grants a monopoly for a discrete period of time, and after it expires the patented subject matter becomes part of the public domain and anyone is allowed to make, use, and sell the relevant products or processes in the free market.[4]

The foundation of patent law is in the U.S. Constitution, which grants Congress the power "[t]o promote the Progress of Science and useful Arts by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[5] This provision, known as the Patent and Copyright Clause, is viewed both as a designation of an enumerated power to Congress and as a limitation on that power—specifically, the

[1] 35 U.S.C. §§ 1–390.
[2] *Id.* § 154.
[3] CRAID ALLEN NARD, THE LAW OF PATENTS 1 (4th ed. 2017) ("A patent gives its owner the right to exclude; a patent does not provide a positive right to make, use, or sell, the invention.").
[4] *See U.S. Patent Overview*, FINDLAW (Dec. 9, 2024), https:/corporate.findlaw.com/intellectual-property/u-s-patent-overview.html (explaining that, once a patent expires, anyone may make, use, offer for sale, or import the invention).
[5] U.S. CONST. art. I, § 8, cl. 8.

Constitution gave Congress the power to "grant[] exclusive rights for limited times."[6] This means patents only grant the right to exclude—thus giving its holder a legal monopoly—without other rights, and those rights must expire after some period of time. Congress has exercised its power to promote the sciences with many different patent laws, from the Patent Act of 1790,[7] its first patent statute, to the 2013 Leahy-Smith America Invents Act[8] (AIA), the first significant overhaul to the patent system in over fifty years.

Patents fall into one of three categories: utility patents, design patents, and plant patents.[9] Utility patents are the concern of most patent law proceedings.[10] Utility patents protect functional ideas ("the way an article is used and works") and issue for a period of twenty years from the filing date of the patent application.[11] Design patents "protect[] the way an article looks" and issue for a period of fifteen years.[12] Plant patents generally protect "distinct and new variet[ies] of plant[s]" such as plants invented or discovered and asexually reproduced.[13]

Modern patent documents consist of two main parts: the specification and the claims.[14] As the Federal Circuit succinctly stated, "[s]pecifications teach. Claims claim."[15] The specification contains the disclosure of the invention, which is used to teach the reader about the particulars of the invention.[16] However, the specification is not a "how-to" guide instructing the average person how to make or perform the invention, rather it contains only enough detail for a person skilled in the art to carry out the invention.[17] In contrast, claims, which are "considered to be the most important part of the patent document," set the legal boundaries of the invention and precisely define the patentee's property rights.[18]

II. BACKGROUND: HOW DO I GET A PATENT?

The patent application process, otherwise known as patent prosecution, starts when an inventor files a patent application with the United States Patent and Trademark Office (USPTO).[19] After the USPTO receives an application, it sends the application to a particular

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[6] NARD, *supra* note 3, at 18.
[7] Act of Apr. 10, 1790, ch. 7, 1 Stat. 109.
[8] Pub. L. No. 112-29, 125 Stat. 284 (2011).
[9] U.S. Patent and Trademark Office, Manual of Patent Examining Procedure § 1502.01 (9th ed. Rev. 01.2024) [hereinafter MPEP] (providing provisions and definitions that cover each of the three types of patents).
[10] *Patents*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/ip-policy/patent-policy/patents (last visited Oct. 5, 2026).
[11] MPEP, *supra* note 9.
[12] *Id.*
[13] *Id.* § 1601; G*eneral Information About 35 U.S.C. 161 Plant Patents*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/patents/basics/apply/plant-patent (last visited Sep. 14, 2026). Without plant patents some kinds of agricultural development would not be cost effective since anyone could simply get seeds of the plant and grow for free what the patent owner had spent time and effort designing. *Id.*
[14] *See* NARD, *supra* note 3, at 47 (noting that claims are technically part of the specification under 35 U.S.C. § 112 but that patent professionals and courts treat claims and specifications as distinct).
[15] SRI Int'l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1121 n.14 (Fed. Cir. 1984).
[16] *Id.* at 1122.
[17] Phillips v. AWH Corp., 415 F.3d 1303, 1323 (Fed. Cir. 2005).
[18] *Id.* at 1118, 1121.
[19] *See* Joshua Scheufler, *Patent*, 27 TEX. INTELL. PROP. L.J. 139, 140–41 (2019) (detailing the PTO process); *Trademark, Patent, or Copyright?*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/trademarks/basics

art unit and Examiner who reviews the patent application for compliance with patent laws.[20] These laws have specific requirements for subject matter eligibility,[21] novelty,[22] non-obviousness,[23] and sufficient disclosure.[24] Throughout the patent prosecution process, the applicant and the USPTO create a "prosecution history" which contains all communications between the parties regarding the patent filed.[25] Any inventions, writings, and patents that came before and are related to a particular application are referred to as "prior art" and examined by the USPTO before deciding whether to issue a patent.[26]

To receive a patent from the USPTO, an applicant must satisfy the three primary statutory requirements of patent eligibility: novelty, non-obviousness, and subject matter eligibility.[27] For an invention to be novel, it must be distinguishable from the prior art. Thus, the invention cannot have been disclosed in a patent, described in a printed publication, in public use, on sale, or otherwise available to the public prior to its effective filing date.[28] Similarly, a patentable invention must be non-obvious—that is, not readily apparent or easily conceivable to a person of ordinary skill in the relevant field.[29] Finally, a patentable invention must refer to patentable subject matter, which is defined by statute as a "process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[30] Typically, subject matters that are not patentable include laws of nature,[31] natural phenomena,[32] and abstract ideas.[33]

/trademark-patent-copyright (last visited Sep. 15, 2026) (explaining the difference between a patent and a copyright).

[20] *See* Sceufler, *supra* note 19. An art unit is a group of patent examiners specified to a technology type. Terry Sheih-Newton & Mark D. Hammond, *Examining Art Units to Avoid Subject Matter Eligibility Challenges for Bioinformatics and AI-Related Patents*, MINTZ (Nov. 18, 2021) https://www.mintz.com/insights-center/viewpoints/2231/2021-11-18-examining-art-units-avoid-subject-matter-eligibility.

[21] Four categories of invention—process, machine, manufacture, or composition of matter—are deemed by Congress to be the appropriate subject matter of a patent. 35 U.S.C. § 101.

[22] The requirement for novelty means that nothing with all of the same elements of the claims can be found in the prior art. *Id.* § 102.

[23] Non-obviousness requires the applicant to demonstrate that they have given society something it didn't have before. *Id.* § 103. The claimed invention must be a non-obvious solution to the person having ordinary skill in the art (PHOSITA). *Id.*

[24] Sufficient disclosure requires that a patent application disclose a claimed invention in sufficient detail so that the PHOSITA could carry out that claimed invention. *Id.* § 112.

[25] Karen Millane Whitney, *Sources of Patent Prosecution History Must Not Violate Public Notice Requirement*, 32 SETON HALL L. REV. 266, 266–68, 268 n.6 (2001).

[26] Whitney, *supra* note 25, at 269–70.

[27] 35 U.S.C. §§ 101, 102, 103.

[28] *Id.* § 102(a).

[29] *Id.* § 103.

[30] *Id.* § 101.

[31] *See, e.g.*, O'Reilly v. Morse, 56 U.S. 62, 113–14 (1853) (holding as ineligible a general claim for using electric current to transmit intelligible signals (telegraphy) because of its broad focus on a law of nature (electromagnetism)).

[32] *See, e.g.*, Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980) (holding that a genetically engineered micro-organism was patentable because it did not otherwise exist in nature).

[33] *See, e.g.*, Alice Corp. v. CLS Bank Int'l, 573 U.S. 208, 226–27 (2014) (rejecting a patent claim as drawn to the abstract idea of intermediated settlement because the claim merely used a generic computer implementation).

III. BACKGROUND: PATENT LAW JUDICIAL BODIES AND PROCEEDINGS

The Federal Circuit has exclusive subject matter jurisdiction over patent appeals and hears all patent appeals from federal district courts, the International Trade Commission (ITC), and the Patent Trial and Appeals Board (PTAB).[34] In 2021, the USPTO filed the highest number of appeals in the Federal Circuit.[35]

Under the AIA, the USPTO has substantially expanded its role in adjudicating the validity of patent claims. The Act created two new types of post-grant proceedings: Post-Grant Review[36] (PGR) and Inter Partes Review[37] (IPR). PGRs review the validity of a patent that has been recently issued, allowing anyone to challenge a patent's validity within nine months of issuance on any ground.[38] The PTAB will grant review if it believes it is "more likely than not" that at least one of the challenged claims is unpatentable on grounds such as subject matter, novelty, public use, or sale.[39] IPRs, on the other hand, permit challenges of a patent's validity after nine months from issuance or, if a party initiated a PGR proceeding, after the PGR terminates.[40] The scope of the challenge in an IPR is narrower than a PGR: grounds for invoking IPR are limited to novelty and obviousness, and must be based only on prior art consisting of patents or printed publications.[41] Further, the Board will not authorize an IPR unless there is a reasonable likelihood that the petitioner will prevail.[42] The decisions to institute both PGRs and IPRs are "final and not appealable;"[43] however, once instituted, a party may appeal an adverse result to the Federal Circuit. These two new methods of review, particularly IPRs, have been very popular due to their economy and efficiency for challenging patents.[44]

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[34] 28 U.S.C. § 1295(a); *see* NARD, *supra* note 3, at 42–43 (explaining that appeals to the Federal Circuit from PTAB may arise from the patent prosecution process, or from patent review proceedings such as Inter Partes and Post Grant Reviews).
[35] APPEALS FILED, TERMINATED, AND PENDING, UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT (2021), https://www.uscourts.gov/sites/default/files/data_tables/jb_b8_0930.2021.pdf.
[36] 35 U.S.C. § 321.
[37] *Id.* § 311. On October 17, 2025, John Squires, the director of the USPTO, stated that he will be "reclaiming the director's statutory role" in deciding whether to institute AIA reviews of patents. *See* Ryan Davis, *USPTO Head to Take Over Patent Review Institution Decisions*, LAW 360 (Oct. 17, 2025, at 16:26 ET), https://www-law360-com.us1.proxy.openathens.net/articles/2401076/uspto-head-to-take-over-patent-review-institution-decisions (noting that while the law states that "such decisions are to be made by the USPTO director . . . that authority has been delegated to the [PTAB] in most cases since the inter partes reviews and post-grant reviews became available in 2012").
[38] 35 U.S.C. § 321(c).
[39] *Id.* § 324(a).
[40] *Id.* § 311(c).
[41] *Id.* § 311(b).
[42] *Id.* § 314(a).
[43] *Id.* §§ 324(e), 314(d).
[44] NARD, *supra* note 3, at 45.

IV. CURRENT PATENT NEWS AND FURTHER READING

A. Proposed Congressional Changes

Congress, backed by the current administration, is pushing a pro-patent agenda in favor of the patent owner through pending legislation.[45] Three bipartisan pieces of legislation, the PREVAIL Act,[46] the Patent Eligibility Reform Act[47] (PERA), and the RESTORE Act,[48] represent a pro-patent agenda that would "(1) limit abusive post-grant patent challenges, (2) clarify what is patentable, and (3) restore the presumption that a patent holder can enjoin (block) infringers from wrongfully using its patented technology."[49] Proponents of these Acts state that they would raise incentives for beneficial patenting that drives innovation.[50]

Specifically, the PREVAIL Act would limit defendant-friendly proceedings concerning patents' ineligibility by raising the standard of proof in IPR proceedings to "clear and convincing" evidence.[51] It also imposes procedural constraints on PTAB proceedings which make it more difficult to challenge patent validity.[52] Opponents of the bill contend that there's a risk that these changes could increase litigation, arguing that strengthening patent protections could extend pharmaceutical monopolies and delay generic competition.[53] The PREVAIL Act was reintroduced to the Senate in May 2025, and remains stalled in committee during the 119th Congress.[54]

Meanwhile, PERA targets the confusion created by the Supreme Court's 2012 *Mayo Collaborative Services v. Promethius Laboratories, Inc.*[55] and 2014 *Alice Corp. v. CLS Bank International*[56] rulings.[57] Such decisions greatly restricted patent eligibility for innovations, especially in software and medical diagnostics.[58] The desired result of PERA would restore a straightforward threshold test for patentability by limiting judicial exceptions and clarifying that "useful processes, machines, manufactures, or compositions of matter are presumptively

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[45] *See* Meaghan Kent, Manyn Caixeiro & Michael Sandonato, *Deregulation Nation: USPTO and the U.S. Copyright Office*, VENABLE LLP (June 10, 2025), https://www.venable.com/insights/publications/2025/06/uspto-and-the-us-copyright-office (explaining that administrative agencies "are shifting discretionary authority away from … bureaucratic administrative judges and administrators" and "toward political appointees" which incentivizes patent enforcement, especially for non-practicing entities, which own patents and receive revenue from licensing or enforcing them, as opposed to gaining revenue from operations).

[46] S. 1553, 119th Cong. (2025); H.R. 3160, 119th Cong. (2025).

[47] S. 1546, 119th Cong. (2025); H.R. 3152, 119th Cong. (2025).

[48] S. 708, 119th Cong. (2025); H.R. 1574, 119th Cong. (2025).

[49] Alden Abbott, *Strong Trump Support for Patent Rights Could Promote U.S. Innovation*, FORBES (June 27, 2025), https://www.forbes.com/sites/aldenabbott/2025/06/27/strong-trump-support-for-patent-rights-could-promote-us-innovation.

[50] *Id.*

[51] Kent et al., *supra* note 45.

[52] *See* Keegan Caldwell, *Trump's First 100 Days: How a Pro-Patent Agenda Could Reshape US Innovation*, CALDWELL (Apr. 25, 2025), https://caldwelllaw.com/news/trump-ip-reform-patent-policy-innovation-impact (explaining that the bill would require anyone challenging a patent to have already been sued or threatened with a patent lawsuit and "prevent multiple challenges against the same patent, apply evidentiary standards favorable to patent owners, and ensure different judges handle the institution and final decision phases").

[53] *Id.* (elaborating that the bill could limit the public's ability to challenge questionable patents through the more accessible PTAB process and possibly force disputes into lengthy and costly federal court proceedings).

[54] CASRAI Editorial Board, *The PREVAIL Act's Stalled 2026 Progress: What the Proposed PTAB Reform Would Mean for Universities*, CASRAI (July 24, 2026), https://casrai.org/news/prevail-act-ptab-reform-university-technology-transfer.

[55] 566 U.S. 66 (2012).

[56] 573 U.S. 208 (2014).

[57] Caldwell, *supra* note 52.

[58] *Id.*

eligible for protection."[59] However, PERA critics are concerned that expanding patent eligibility to include subject matter that was previously considered natural phenomena or abstract ideas could allow companies to claim broader ownership over biological information or fundamental concepts.[60] On July 14, 2026, the full Senate Judiciary Committee held its first full committee session on PERA, titled "From Genes to Machines: The Patent Eligibility Debate."[61] Four witnesses testified at the hearing, evenly split.[62] The discussion focused on whether §101 reform is necessary in advancing technology sectors, including medical diagnoistics and AI.[63] The hearing was closed by acknowledging that "many members are still studying the bill," and no committee markup or vote was scheduled as of the hearing date.[64]

While PERA would likely redefine the law of patent eligibility by eliminating judicial exceptions, the RESTORE Act would create a presumption in favor of injunctions.[65] The RESTORE Act was reintroduced in February 2025 and is awaiting further action by the judiciary committees.[66] Before 2005, if patent owners proved patent infringement, they were given an injunction as a matter of course.[67] Starting in 2006, the post-*eBay Inc. v. MercExchange, LLC*[68] framework made it nearly impossible for non-practicing entities (NPEs) to obtain injunctions.[69] However, RESTORE could recalibrate the power dynamic in favor of NPEs.[70]

B. USPTO Hiring and Employment Status

On January 20, 2025, President Trump signed an executive order that froze all federal hiring and required federal employees to return to in-person work.[71] Although the USPTO is largely self-funded through user fees, executive actions aimed at reducing federal spending nevertheless apply.[72] The hiring freeze prevented the USPTO from bringing on about 800

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[59] *Id.*
[60] *Id.*
[61] *From Genes to Machines: The Patent Elgibility Debate: Hearing before the S. Comm. on the Judiciary*, 119th Cong. (2026).
[62] CASRAI Editorial Board, *Senate Judiciary's July 2026 PERA Hearing: Stakes for University Diagnostics and AI Patents* (July 24, 2026), https://casrai.org/news/senate-judiciary-pera-hearing-2026-diagnostics-ai.
[63] Kirsten Donaldson, *Is the 4th Time a Charm? Congress Revisits Patent Eligibility Reform*, HOLLAND & KNIGHT (July 21, 2026), https://www.hklaw.com/en/insights/publications/2026/07/is-the-4th-time-a-charm-congress-revisits-patent-eligibility-reform. *See generally* Mags Martin, *PERA-Phrasing the Judicially Created Patent Eligibility Doctrine: Pros and Cons of Rewriting Section 101*, SHEPPARD MULLIN RICHTER & HAMPTON LLP (Aug. 7, 2026), https://www.sheppard.com/insights/blogs/pera-phrasing-the-judicially-created-patent-eligibility-doctrine-pros-and-cons-of-rewriting-section-101 (providing a summary of the witness testimony offered during the PERA hearing and a general background of the issues presented within PERA).
[64] CASRAI Editorial Board, *supra* note 62.
[65] Kent et al., *supra* note 45.
[66] S. 708, 119th Cong. (2025).
[67] Kent et al., *supra* note 45.
[68] 547 U.S. 388 (2006).
[69] Kent et al., *supra* note 45.
[70] *Id.*
[71] Grant M. Ehrlich & Youngmin Lee, *Patent Strategies in Response to Recent U.S. Developments: Expected Changes and Filing Strategies*, STITES & HARBISON PLLC (June 10, 2025), https://www.stites.com/resources/client-alerts/patent-strategies-in-response-to-recent-u-s-developments-expected-changes-and-filing-strategies.
[72] Dennis Crouch, *USPTO Facing Additional Cuts: What's Core vs. Expendable*, PATENTLY-O (Feb. 26, 2025), https://patentlyo.com/patent/2025/02/facing-additional-expendable.html.

new hires, many of whom were patent examiners.[73] Furthermore, for over twenty years, the USPTO operated on a remote work model, and to comply with the executive order, it had to force 90% of its workforce to return to physical offices that did not exist.[74] In response to these drastic changes and low demand for the service, the USPTO has discontinued its Accelerated Examination program for utility and design applications.[75] This workforce reduction was compounded by October 2025's government shutdown; within twenty-four hours of the shutdown, the USPTO announced that one of its regional offices would be closed and employees laid off.[76]

The USPTO is in an active hiring and rebuilding phase throughout 2026, particularly recruiting patent examiners and other employees to address workload and processing backlogs.[77] The USPTO's increased hiring efforts supports continued backlog reduction, with the total number of unexamined patent applications falling to 776,995 as of April 2026 from a high of 837,928 in January of 2025.[78] During 2026, the USPTO has completed multiple hiring periods, aiming to hire 900 new examiners by October of 2026.[79] Furthermore, the USPTO has implemented a series of operational and performance-management changes during 2026.[80]

C. AI and Patent Law

Between 2000 and 2022, approximately 190,000 Artificial Intelligence (AI) patents were granted worldwide,[81] and as AI has developed, courts have found it challenging to set precedent regarding AI patentability. In the 2022 decision in *Thaler v. Vidal*,[82] the Federal Circuit affirmed that AI inventions can be patented, but the inventor listed on the patent application must be a natural person—not the AI itself.[83] But the holding in *Thaler* did not go so far as to conclude whether inventions made possible by the assistance of AI or

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[73] Ehrlich & Lee, *supra* note 71.
[74] *Id.*
[75] *USPTO Discontinuing Accelerated Examination Program for Utility Applications*, U.S. PAT. & TRADEMARK OFF. (June 9, 2025), https://www.uspto.gov/about-us/news-updates/uspto-discontinuing-accelerated-examination-program-utility-applications; *USPTO to Suspend Expedited Examination of Design Applications*, U.S. PAT. & TRADEMARK OFF. (Apr. 14, 2025), https://www.uspto.gov/about-us/news-updates/uspto-suspend-expedited-examination-design-applications.
[76] Jory Heckman, *USPTO, Sends Layoff Notices After Trump Administration Threatened Shutdown RIFs*, FED. NEWS NETWORK (Oct. 1, 2025), https://federalnewsnetwork.com/government-shutdown/2025/10/uspto-sends-layoff-notices-after-trump-administration-threatened-shutdown-rifs.
[77] *USPTO Jobs*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/jobs/join-us (last visited Sept. 14, 2026).
[78] *USPTO Turns Corner on Unexamined Patent Application Backlog Reduction*, U.S. PAT. & TRADEMARK OFF. (Apr. 6, 2026), https://www.uspto.gov/about-us/news-updates/uspto-turns-corner-unexamined-patent-application-backlog-reduction.
[79] Dani Kass, *USPTO Wants 900 New Patent Examiners by October*, LAW360 (Mar. 25, 2026), https://www.law360.com/articles/2452486/uspto-wants-900-new-patent-examiners-by-october.
[80] Roland Casillas, *Impacts of Recent USPTO Examiner Workflow Changes*, BOOKOFF MCANDREWS (July 8, 2026), https://www.bomcip.com/blog/impacts-of-recent-uspto-examiner-workflow-changes/.
[81] *Global Competitors Outpace U.S. in Patents*, U.S. NAT'L SCI. FOUND. (Feb. 29, 2024), https://www.nsf.gov/nsb/updates/global-competitors-outpace-us-patents.
[82] 43 F.4th 1207, 1209 (Fed. Cir. 2022).
[83] *See id.* at 1209, 1211–12 (analyzing the inventorship requirement using the plain meaning and legal precedent relating to the word "individual" in the Patent Act). Technologies like generative AI can create original works, like images, music, and writings, but these original works are hallucinations based on machine-learning models developed by humans. *See* Adam Zewe, *Explained: Generative AI*, MIT NEWS (Nov. 9, 2023), https://news.mit.edu/2023/explained-generative-ai-1109.

inventions generated entirely by AI are patentable.[84] In 2024, the USPTO released guidance on AI and patent inventorship and concluded that both the inventor and coinventor of an invention must be a natural person.[85] The guidance also addressed whether an invention can be patented if AI was used to assist in its invention.[86] The USPTO concluded that so long as only natural persons are named as the inventors, and each named natural persons significantly contributed to creating the invention in accordance with the factors listed in *Pannu v. Iolab Corp.*,[87] patentability of an invention is not precluded by AI assistance.[88] The guidance provided by the USPTO aligns with the purpose of the patent system: "to encourage *human* ingenuity."[89]

D. Pharmaceuticals and Patent Law

Patents are essential to the pharmaceutical industry, granting drugmakers exclusive rights to sell treatments and recover research and development costs.[90] However, this often means that companies protect their individual products with more than one patent, often called "patent thickets." [91] Patent thickets are often critiqued for blocking or delaying generic entry into the market, resulting in perpetuation of high drug prices.[92] Legislation such as the Eliminating Thickets to Increase Competition Act[93] (ETHIC Act) and the Medication Affordability Patent Integrity Act[94] aim to address the patent thicketing issue.[95] The ETHIC Act is a bipartisan legislative proposal designed to lower drug prices by restricting how pharmaceutical companies use overlapping patents during legal disputes.[96] The Medication Affordability Patent Integrity Act was created to lower prescription drug costs and stop pharmaceutical companies from withholding information from the USPTO in order to secure secondary patents.[97] These Acts reflect tensions between patent exclusivity rights and generic competition necessary to lower drug costs.

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[84] 43 F.4th at 1213.
[85] Inventor Guidance for AI-Assisted Inventions, 89 Fed. Reg. 10,043, 10,045–46 (Feb. 13, 2024).
[86] *Id.* at 10,046.
[87] 155 F.3d 1344 (Fed. Cir. 1998).
[88] Id. at 1351 (listing the elements an inventor or coinventor must satisfy) ("(1) [C]ontribute in some significant manner to the conception or reduction to practice of the invention, (2) make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention, and (3) do more than merely explain to the real inventors well-known concepts and/or the current state of the art."); Inventor Guidance for AI-Assisted Inventions, 89 Fed. Reg. 10,043, 10,046 (Feb. 13, 2024).
[89] Inventor Guidance for AI-Assisted Inventions, 89 Fed. Reg. 10,043, 10,046 (Feb. 13, 2024).
[90] Blockbuster Drugs Face a Massive Patent Cliff in 2026, DRUG DISCOVERY NEWS (Feb. 24, 2026), https://www.drugdiscoverynews.com/blockbuster-drugs-face-a-massive-patent-cliff-in-2026-17019.
[91] Michale Carrier & Dean S. Tu, *Why Pharmaceutical Patent Thickets Are Unique*, 32 TEX. INTELL. PROP. L. J. 79, 80 (2024) (highlighting that a single drug can have more than 100 patents).
[92] *See id.* at 83.
[93] S. 2276, 119th Cong. (2025); H.R. 3269, 119th Cong. (2025).
[94] S. 2658, 119th Cong. (2025).
[95] Caitlin Rowley Gallamore & Anna Spahn, *Bipartisan Momentum on Drug-Patent Reform Could Clear a Faster Path for Affordable Generics*, NISKANEN CTR. (July 9, 2026), https://www.niskanencenter.org/bipartisan-momentum-on-drug-patent-reform-could-clear-a-faster-path-for-affordable-generics/.
[96] H.R. 3269, 119th Cong. (2025). *See* Press Release, Rep. Jodey Arrington, Arrington Introduces ETHIC Act to Increase Competition in the Prescription Drug Market (May 9, 2025) https://arrington.house.gov/news/documentsingle.aspx?DocumentID=2738.
[97] Press Release, Sen. Maggie Hassan & Sen. Josh Hawley, Senators Hassan and Hawley Introduce Bipartisan Legislation to Combat Big Pharma's Patent Abuse and Lower Prescription Drug Costs (Aug. 25, 2025)

This tension becomes more apparent as patents approach expiration. Once a drug patent expires, the market shifts as cheaper generics enter, leading to price reductions and reduced revenue for patent-holding pharmaceutical company.[98] In 2026, the pharmaceutical industry is entering its biggest wave of patent expirations—often referred to as a patent cliff—disrupting billions in annual sales for drugmakers.[99] The anticipated loss of exclusivity has intensified litigation between brand-name drugmakers seeking to introduce competing products. For example, Bristol Myers Squibb and Ono Pharmaceuticals have filed a lawsuit against Amgen, seeking to block Amgen's proposed biosimilar of their cancer immunotherapy drug Opdivo.[100] While Bristol Meyers aims to defend its market exclusivity until 2028, when its primary patent protections are set to expire, challengers like Amgen are actively trying to enter the market early.[101] Recent litigation also demonstrates tensions between pharmaceutical patent rights and government efforts to reduce drug prices. In *Amgen Inc. v. Mizner*,[102] Amgen challenged Colorado's effort to impose an upper payment limit on its arthritis drug Enbrel, arguing that state price regulation is preempted by federal patent law.[103] The court found that Colorado's acts interfered with Amgen's patent exclusivity, barring Colorado from implementing an upper payment limit.[104] This final district court judgment was subsequently appealed to the U.S. Court of Appeals for the Federal Circuit.[105] As states increasingly explore mechanisms to control the prices of medicines, *Amgen* illustrates the potential conflict between these regulatory efforts and the rights afforded by federal patent law.

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https://www.hassan.senate.gov/news/press-releases/senators-hassan-and-hawley-introduce-bipartisan-legislation-to-combat-big-pharmas-patent-abuse-and-lower-prescription-drug-costs.

[98] DRUG DISCOVERY NEWS, *supra* note 90.

[99] Xavier Martinez, *Pharma Industry Stares Down Biggest Patent Cliff in Decades*, WALL ST. J. (Aug. 29, 2026), https://www.wsj.com/health/pharma/pharma-industry-stares-down-biggest-patent-cliff-in-decades-2d96c4cd (stating that "more than $500 billion of projected global sales are at risk of losing patent protection by 2033").

[100] Bristol Myers Sues Amgen over Proposed Opdivo Biosimilar, REUTERS (Sept. 15, 2026), https://www.reuters.com/legal/litigation/bristol-myers-sues-amgen-over-proposed-opdivo-biosimilar-2026-09-15/.

[101] *Id.*

[102] Amgen Inc. v. Mizner, 836 F. Supp. 3d 1127 (D. Colo. 2026).

[103] *See* Amgen Inc. v. Mizner, No. 1:25-cv-03452-DDD-STV, 2026 WL 1943512, at *1–2 (D. Colo. May 15, 2026); Andrew Twinamatsiko & Katie Keith, *What's Next for Prescription Drug Affordability Boards After* Amgen v. Mizner*?*, HEALTH AFFS. (July 16, 2026), https:www.healthhaffairs.org/content/forefront/s-next-prescription-drug-affordability-boards-after-amgen-v-mizner.

[104] Amgen Inc. v. Mizner, 2026 WL 1943512, at *4.

[105] Amgen Inc. v. Mizner, 836 F. Supp. 3d 1127 (D. Colo. 2026), *appeal docketed*, No. 26-2111 (Fed. Cir. Aug. 4, 2026).